REMARKS/ARGUMENTS

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claims 10, 12-14, 18, 28, 30-32 and 36 have been amended to define more clearly the patentable invention applicant believes is disclosed herein. New claims 37-39 have been added. Moreover, claims 11, 15, 29, and 33 have been cancelled. Claims 1-9, 17, 19-27, and 35 were previously cancelled. Claims 16 and 34 are unchanged by the present amendment paper. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The Examiner continues to reject all of the pending claims (i.e., claims 10-16, 18, 28-34 and 36) as being unpatentable over the prior art. In particular, the Examiner has cited U.S. Patent No. 5,789,175 to Priest; U.S. Patent No. 4,205,043 to Esch et al.; U.S. Patent No. 6,087,089 to Wu; U.S. Patent No. 5,770,150 to Thornton et al.; and U.S. Patent No. 6,488,890 to Kirchkof.

In an effort to expedite prosecution of the present application, the independent claims of the present application (i.e., claims 10 and 28) have been amended to more clearly define the applicant's invention. It should be appreciated that the present invention includes a plurality of indicator panels, each of which has a differing amount of thiosulfate thereon. Accordingly, each of the plurality of indicator panels will undergo a *single permanent* color change after a different exposure time to a concentration of vaporized hydrogen peroxide. The *single permanent* color change will be produced by depletion of thiosulfate and an accumulation of triodide ions, as discussed in detail at paragraph [0021] of the present application (see page 6). Accordingly, the amount of thiosulfate on the indicator panel will directly affect the time at which a color change will occur in the presence of a minimum desired concentration of vaporized hydrogen peroxide. In other words, the amount of thiosulfate on each indicator panel will determine how much vapor phase hydrogen peroxide can react with the thiosulfate before the *single permanent* color change occurs. It is believed that chemistry responding with a single permanent color change is simpler and more reliable than chemistry that responds with multiple color changes.

By determining the desired VHP concentration and the desired VHP exposure time, an appropriate amount of thiosulfate can be applied to each indicator panel, wherein each indicator panel will respectively change color only when the minimum desired VHP concentration is present for a minimum desired exposure time. Therefore, the amount of thiosulfate on each indicator panel will determine how much vapor phase hydrogen peroxide can react with the thiosulfate within a certain time interval before the single permanent color change occurs. Accordingly, the less thiosulfate on an indicator panel, the sooner a color change will be observed when the indicator panel is exposed to vapor phase hydrogen peroxide. Since each of the plurality of indicator panels has a different amount of thiosulfate thereon, the time interval at which a single permanent color change will be observed for each indicator panel will be different upon exposure to the vapor phase hydrogen peroxide.

It should be further appreciated that independent claims 10 and 28 require a plurality of indicator panels that undergo a *single permanent* color change after a different exposure time to a minimum concentration of vaporized hydrogen peroxide. Therefore, once an indicator panel has undergone a color change, no further color changes can occur due to depletion of the thiosulfate, and the accumulation of triodide ions.

Turning now to the Priest reference, it is noted that Priest uses an identical chemistry throughout the chemical indicator disk 42. Accordingly, insufficient sterilant in a sterilization cycle will cause a missing spot and a larger than expected spacing between adjoining spots on the chemical indicator disk 42 (see column 5, lines 3-5). Each and every space on the chemical indicator disk 42 that is exposed to the sterilant will respond in exactly the same manner, since the chemistry is identical throughout the chemical indicator disk 42. In contrast, each of the indicator panels of the claimed invention have a different chemistry (i.e., a different amount of thiosulfate) such that the exposure time to a minimum concentration of vaporized hydrogen peroxide required to cause a single color change will differ for each indicator panel. Priest's invention also requires the use of a complex "pressure actuated exposure mechanism" in order to effectively use the chemical indicator disk 42.

Referring now to Esch et al., this reference discloses a plurality of disks that undergo multiple color changes in sequence from green to orange and then from orange to red in response to dosages of toxic gases encountered in a fire atmosphere. Therefore, the chemistry

taught by Esch et al. is also significantly different from the chemistry of the claimed invention, since the chemistry of the claimed invention produces only a single permanent color change. Accordingly, it is respectfully submitted that the chemistry used by Esch et al. is more complex than the chemistry of the claimed invention, and requires multiple color changes for effective use of the indicator.

Referring now to Wu, this reference teaches at column 6, lines 66-67 and column 7, lines 1-10 (emphasis added):

> "[i]n accordance with an important feature of the present invention, the iodine-polymer complex undergoes a *color transition* through various detectable and measurable degrees and intensities of color such that the degree and intensity of the *color transition* can be correlated to the concentration of oxidant in a test sample. In accordance with another important feature of the present invention, the indicator reagent composition undergoes a *differentiable color transition* at high oxidant concentrations, and, therefore, it is unnecessary to dilute the test sample. The ability to assay an undiluted test sample eliminates a common source of error from the assay."

In contrast to Wu, the indicator panels of the applicant's claimed invention undergo a single color change after exposure to a minimum amount of vaporized hydrogen peroxide (for a given exposure time). Wu also does not teach or suggest using chemistry of differing amounts of thiosulfate for a plurality of indicator panels.

It should be appreciated that the claimed invention requires a plurality of indicator panels having a chemistry thereon that comprises iodide and thiosulfate. Each of the plurality of indicator panels have a different amount of thiosulfate thereon, and thus each of the plurality of indicator panels will undergo a single permanent color change after a different exposure time to a minimum concentration of vaporized hydrogen peroxide.

Priest differs from the claimed invention in that this reference requires a complex mechanical device and the chemistry is uniform throughout the indicator disk. The Esch et al. reference differs from the claimed invention in that it does not teach or suggest the use of a chemistry that only undergoes a single permanent color change, and does not contemplate detection of vaporized hydrogen peroxide. Wu teaches away from the claimed invention in that it highlights and emphasizes the advantages of using a chemistry that provides detectable and

measurable degrees in intensity of color transitions. Wu also does not teach or suggest using chemistry of differing amounts of thiosulfate for a plurality of indicator panels.

It is also respectfully submitted that Thornton et al. and Kirchof do not teach or suggest the invention as defined by the present claims.

Newly added independent claim 37 defines an indicator having a carrier strip with a plurality of discrete sections, "wherein each said section will undergo a *single permanent color change* when exposed to said minimum concentration of vaporized hydrogen peroxide *for a respective select portion of said decontamination cycle*." Accordingly, it is respectfully submitted that independent claim 37, and claims 38 and 39 which depend therefrom, are likewise patentable over the cited references for the reasons discussed above.

Moreover, it should be noted that the sections of the carrier strip defined by new independent claim 37 are used to determine the presence of a *minimum concentration* of vaporized hydrogen peroxide during *select portions* of a decontamination cycle. In other words, the sections of the claimed carrier strip allows one to determine whether a minimum concentration of vaporized hydrogen peroxide has been maintained during multiple fixed time segments of a decontamination cycle. In contrast, the multi-disk indicator of Esch et al. is used to monitor a gas dosage over an undefined time period, namely, the total time period during which a firefighter is located within a fire atmosphere. As indicated above, each section of the applicant's carrier strip will change color after a minimum concentration level of vaporized hydrogen peroxide has been maintained for a select time segment of the decontamination cycle.

In addition to the foregoing arguments for patentability, the applicant also fully incorporates by reference the arguments presented in the prior Response dated February 9, 2006. In this regard, the applicant continues to maintain that a *prima facte* case for obviousness has not been established. The applicant respectfully disagrees with the Examiner's "obviousness" combination based upon the rationale that Esch et al. provides "an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner." It is further submitted that the arguments presented above with regard to the deficiencies of Priest, Esch et al. and Wu further support the applicant's reasoning that there is a lack of motivation or suggestion to one skilled in the art to combine select teachings of the foregoing references.

In the Examiner's "Response to Arguments" the Examiner notes:

> Table 1 of Esch et al., found in column 3, clearly cited well known sterilants as chemicals capable of being monitored by the indicator, namely, chlorine dioxide, chlorine and ethylene oxide. The Examiner would further note that Wu clearly equates the sterilants of chlorine and peroxide. Thus the requirements of *prima facie*, are clearly and properly met in the rejections above.

With respect to the Examiner's argument concerning the teachings of Esch et al. and Wu, it should be appreciated that the applicant's claimed invention is specifically directed to ***vaporized hydrogen peroxide*** used in a decontamination chamber. While the "badge detectable gasses" of Table 1 of the Esch et al. reference does identify chlorine, chlorine dioxide, and ethylene oxide, it is submitted that Esch et al. specifically omit "hydrogen peroxide" because Esch et al. teach a badge that is directed specifically to the detection of dangerous gasses in a ***fire atmosphere***. Since "vaporized hydrogen peroxide" is not a toxic gas typically found in a fire atmosphere, it is respectfully submitted that one of ordinary skill in the art would not be motivated to use the badge device of Esch et al. for detection of vaporized hydrogen peroxide. The foregoing further supports the applicant's argument that one skilled in the art, without the benefit of hindsight, would not combine the teachings of Esch et al. with the pressure actuated ***sterilant indicator*** of Priest ***for use in a controlled sterilant receiving environment***, or the peroxide and chlorine test strip of Wu, ***contemplated for use in a food processing or medical environment*** (see column 1, lines 26-34). In this regard, neither Priest nor Wu teaches devices that are used in an environment similar to a "fire atmosphere."

In summary, Esch et al. is directed to a badge indicator that is to be worn by a human that will be entering a "fire atmosphere" wherein there is potential exposure to airborne toxic gasses produced by a fire. In contrast, Priest is concerned with detecting whether the required pressure and sterilant vapor concentrations are achieved in a sterilant receiving environment during a controlled sterilization process, and Wu is concerned with detecting peroxide and chlorine that is used as a sanitizer or disinfectant in food processing equipment and medical equipment, such as a hemodialysis unit. In view of the foregoing, it is respectfully submitted that one of ordinary skill in the art at the time the invention was made would not have been motivated to combine teachings of Esch et al. with the teachings of Priest or Wu, since the

device of Esch et al. is clearly limited to use in a "fire atmosphere," which would exclude use of Esch et al.'s device for detection of vaporized hydrogen peroxide.

In view of the foregoing, it is respectfully requested that the Examiner withdraw the 35 USC 103 rejections and allow the application.

If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8011US.

Respectfully submitted,

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